UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

MSP CORPORATION, a Minnesota corporation,

Plaintiff,

vs.

WESTECH INSTRUMENTS, INC., a Georgia corporation; WESTECH INSTRUMENT SERVICES LTD., a United Kingdom corporation; and WESTECH INSTRUMENT HOLDINGS, PLC, a United Kingdom corporation,

Defendants.

Civil No. 07-CV-2301 (MJD/SRN)

AFFIDAVIT OF DARYL ROBERTS

STATE OF MINNESOTA)
) ss.
COUNTY OF RAMSEY)

DARYL ROBERTS, being first duly sworn upon oath, deposes and states as follows:

1. I have a doctorate in chemical engineering from the California Institute of Technology. I joined MSP Corporation in April 1998, and my first responsibility was to serve as Product Manager for development of the Next Generation Impactor ("NGI"). I have been with MSP since 1998 and am currently a Vice President. I have personal knowledge of the facts stated in this affidavit, and I make this affidavit in support of MSP Corporation's motion for a preliminary injunction against Westech.

2. MSP was founded in 1985 by two mechanical engineering professors from the University of Minnesota, Virgil Marple and Benjamin Liu. Professors Marple and Liu are among the leading researchers and authorities on aerosols and airborne particles in the world. Their academic research at the University of Minnesota led to technologies with significant commercial applications, and, with the University's blessing, they started MSP to commercialize some of those innovations. Exhibit A is memorandum summarizing MSP's history submitted as part of MSP's application for the Tibbets Award, which recognizes outstanding research and entrepreneurship by small businesses. Professor Liu, Professor Marple, and MSP have received numerous awards and recognition for their groundbreaking research and products in the aerosol and particle-technology fields.

3. MSP has introduced numerous commercially successful products in several fields. MSP's wafer deposition system enables computer chip manufacturers to place particles on silicon wafers, a preeminent and cutting-edge product purchased by virtually every computer chip manufacturer in the world. MSP also specializes in precise, research-grade measurements of airborne particles, and its measurement devices fulfill air sampling needs in industrial health and pollution control. MSP's aerosol expertise also has important applications for manufacturing and development of inhaled medicines, which are dispensed through dry-powder, metered-dose, or similar aerosol inhalers.

4. Based in Shoreview, Minnesota, MSP remains a relatively small, yet highly successful company. MSP had eight employees when I started in 1998. Today, it has 40 employees. MSP continues to possess an outstanding reputation for innovation and

production of products with impeccable quality. In fact, given the nature and application of its products, MSP's commercial success depends on a reputation for selling products of unparalleled precision, reliability, and accuracy. Based on this reputation, MSP has sold products throughout the United States and the world.

5. Inhaled medicines are dispensed via inhalers that deliver dry-powder or other aerosols. Each activation (for the patient, each "puff") of the inhaler dispenses a dose of active medicine and typically also inactive particles that deliver the medicine. (The inactive particles are often referred to as "carrier particles.") To research, develop, manufacture, and ultimately mass-produce inhalers, pharmaceutical companies must precisely measure the amount and size of active medication in each dose delivered by the inhaler. In particular, pharmaceutical companies rely on impactors for quality assurance during the manufacturing process after inhaled medicines have been approved by the FDA. Accuracy is essential for safe, reliable, and efficacious inhalers. Pharmaceutical companies use cascade impactors to make these measurements.

6. The first impactor still used today for inhaler testing was developed in the 1940's. Called the Andersen Impactor, it was developed for military applications, in particular, measurement of smoke particles. For decades, the Andersen Impactor was the only device capable of measuring inhaled medications. Despite the pharmaceutical companies' dependence on the Andersen Impactor to develop inhalers, it has several shortcomings. It lacks accurate performance and calibration. The Andersen Impactor consists of several stages, and particles separate by size as the airflow proceeds through the stages. The Andersen Impactor is susceptible to "stage overlap," meaning that bigger

particles that should be trapped in early stages escape to a later stage and smaller particles that should escape to latter stages are trapped prematurely. Stage overlap results in inaccurate measurements.

7. Historically, several companies developed and sold competing Andersen Impactors. Differences between models and manufactures lead to subtle, but potentially critical, measurement differences. Consequently, testing results from multiple Andersen Impactors can have substantial differences. This can create severe problems for validating research results and ultimately obtaining regulatory approval from the FDA. When reviewing an application for inhaled medicines, the FDA may reject inconsistent laboratory results conducted using different Andersen Impactors.

8. The limitations of and variance between Andersen Impactors came to a head in the 1980's when inhalers were required to be reformulated without use of CFCs or freon. That requirement forced the pharmaceutical to develop new inhaler designs and to obtain FDA approval of those inhalers. Variance in measurements resulting from use of different Andersen Impactors lead to regulatory delays, which were and can be extraordinarily costly.

9. In response, a group of 15 pharmaceutical companies that produce inhaled medicines created the Next Generation Impactor Consortium. The Consortium sought to develop an impactor with improved performance and accuracy. More importantly, the Consortium sought uniformity. Its goal was to develop one impactor that delivers consistent results and eliminates measurement variance between multiple models. If achieved, this uniformity would eliminate the need for scrutiny of the techniques and

devices used to test inhaled medicines. It would also enable pharmaceutical companies to have one, consistent measurement device to achieve maximum quality assurance during the manufacturing process.

10. In 1998, the Consortium selected MSP to develop the new impactor. MSP was selected based on the reputation of its founders for preeminence in the field of aerosol measurement, instrumentation, and testing. After two years of development, MSP completed a prototype of an impactor it called the Next Generation Pharmaceutical Impactor ("NGI"). Attached as Exhibit B is the NGI User Guide describing the NGI device.

11. The NGI device revolutionized impactor technology and included a number of innovations that dramatically improved the function, performance, and efficiency of the impactor in comparison to the Andersen Impactor. Among other things, improvements included:

- a flat, rather than vertical, design that facilitates ease of use;
- a "pre-separator" device, for which MSP obtained a patent, that cleanly separates inactive carrier particles from active medication before the active drug particle enter the cascade stages;
- precisely fixed and shaped airflow nozzles that ensure accurate and consistent air speed;
- eight collection cups with precisely known dimensions and with a tear-drop shape and specially designed passageways between cups to ensure accurate separation of drug particles by size; and

- a patented "micro-orifice collector" as the eighth and final stage that captures the tiniest particles, eliminates fibrous filters used in the Andersen Impactor, and controls the start-up kinetics of the impactor.

Numerous other design decisions unique to the NGI device resulted in a new impactor delivering significant improvements in ease of use, reliability, accuracy, and efficiency. MSP obtained multiple patents for NGI technology. During the development process, MSP sought to design a product that would meet the Consortium's specific needs. While the NGI Consortium provided input into the process, MSP actually designed and developed the NGI device.

12. MSP's prototype was subjected to rigorous testing by members of the Consortium. After MSP improved the prototype, the second prototype was devised by MSP and approved by the Consortium. The accuracy of the NGI device was demonstrated in peer-reviewed journal articles. The Consortium, pharmaceutical companies around the world, and the FDA accepted the NGI as the standard-setting measurement device for inhalers. The Consortium determined that the NGI device met its need for uniform, consistent, reliable measurements in which companies and government agencies can have complete confidence.

13. Having obtained approval of the prototypes, MSP developed the ability to manufacture and commercialize the NGI device, and it has been a highly successful product. MSP has sold over 400 NGI devices to dozens of companies around the world for use in the research, development, and manufacture of inhaled medicines. MSP has

been the only company that manufactures the NGI device or comparable impactor technology; although the Andersen Impactor remains available, virtually every pharmaceutical company purchasing a new impactor or initiating new inhaler projects has purchased the NGI device since its introduction.

14. The success of the NGI device depends on its reputation for impeccable accuracy and reliability. Its commercial success is also tied to the Consortium's purpose, namely development of one impactor delivering uniform results. The NGI device sets the standard for pharmaceutical particle measurement. Given the importance of maintaining perfect consistency and quality between devices, MSP tracks the destination of each NGI device sold. MSP knows the customer and location where each serially numbered NGI device has been placed. This level of monitoring and care helps to protect MSP's reputation for quality, service, and excellence.

15. MSP has also identified the NGI device with several unique distinguishing features. The "Next Generation" and "NGI" names connote the fact that the device has been tested and endorsed by the Consortium. The bottom of the NGI device was painted a royal blue color that matches MSP's company colors and logo. The NGI device has a unique and distinctive shape. All of these identifying features have been used with the NGI device since it was introduced to the market. None of these features is related to the function of the NGI device or assists its measurements, and MSP considers these features to be trademarks. Attached as Exhibit C are pictures of early versions of impactors taken during MSP's product development process. The pictured versions have rectangular shapes, a design that would have been just as functional as the chosen puzzle-piece shape.

The outside of the impactor could be given any number of shapes without affecting its measurement function. The external shape of the impactor has no bearing on the aerodynamic properties of the internal components, which dictate the measurement purpose of the device. MSP chose a puzzle-piece shape to achieve an interesting, unique, artistic design that distinguishes the NGI device as an MSP product. MSP designs many of its products to have visually interesting and unique designs. Machining the NGI device to produce the puzzle-piece shape is more costly and time consuming than using a generic shape, such as a rectangle or square.

16. These trademarks identify the NGI device as MSP's product and associate the NGI device with MSP's reputation for reliability and quality. They also designate the NGI device as the impactor that has been approved by the Consortium and established as the industry standard for particle measurement. MSP advertises and promotes the NGI device with these marks, and the NGI device is universally associated with MSP.

17. Many of the NGI device's features are arbitrary and could be performed in multiple ways. To name a few, such features include: left-to-right airflow, location of airflow intake and exhaust, placement and shape of the clamping mechanism, the optional handle, and the means of fixing the distance between the nozzle and collection cups. All of these features reflected decisions during the design process.

18. MSP first learned of Westech's new impactor when Westech requested a meeting with us in January 2007. That meeting occurred when Westech's Mike Smurthwaite traveled to Minnesota to meet with Professor Liu, Professor Marple, and me on January 24. At that meeting, Mr. Smurthwaite did not mention that he had completed

development of an impactor. Nor did he show us any pictures of his designs or bring the device. He mentioned only that he had some intentions to manufacture a device similar to the NGI device. Because his plans and purposes were not clear, Dr. Liu requested that he put in writing what he wanted from MSP.

19. Mr. Smurthwaite sent a letter to me on February 5, 2007. That letter asserted that MSP had reached an agreement with Westech allowing it to sell a "Next Generation Impactor" that Westech had developed. The letter claimed that MSP had no objections to Westech selling an "NGI." In fact, we never discussed any such agreement at the January 24 meeting, and no one from MSP ever made any statement to Mr. Smurthwaite that could possibly be construed as accepting, without objection, Westech's marketing of a competing product. Consequently, I responded within minutes to Mr. Smurthwaite's letter telling him that we did not agree. Mr. Smurthwaite's dealings with MSP are not consistent with MSP's approach to conducting business in an upfront and good-faith manner.

20. When I saw Westech's impactor for the first time, I was shocked. It appeared to copy every aspect of the NGI device. The color, shape, appearance, and components of Westech's impactor were visually identical. All of the design decisions made in development of the NGI were copied in virtually every respect. Even as the Product Manager for the development of the NGI device and perhaps the most knowledgeable person in the world about it, I had a difficult time visually distinguishing the real NGI device from pictures of Westech's version. Additionally, on April 12, 2007, I visited Westech's website and read its description of the new impactor. I have attached as

Exhibit D a copy of the webpage I viewed on April 12. It calls the Westech version the "Next Generation Impactor" and falsely indicates that it was approved by the Consortium.

21. I have since learned that Westech has begun actively marketing its impactor. Among other things, it has sent email advertisements to prospective customers, which I believe include customers located here in Minnesota. My understanding is that Westech has made sales calls to Minnesota and has sold products here.

22. I have profound concerns that impactor customers will mistake Westech's impactor for MSP's real and approved NGI device. Westech's decision to copy virtually all external features of the NGI creates that risk. Also, impactors are often sold through third-party distributors. A company buying an impactor from a distributor may have no indication that the visually identical Westech impactor is not the real NGI. Westech distributes certain devices manufactured by other companies, and a customer could easily believe it is buying an NGI if purchasing directly from Westech. In the past, Westech distributed some of the products manufactured by MSP, increasing the likelihood that some consumers might believe there is a connection between MSP and Westech. In fact, customers have asked me whether Westech is now an authorized distributor of MSP products. Finally, Westech's product promotions have created further risk of confusion because it has referred to its product as the NGI and claimed that its impactor has been approved by the Consortium. The Consortium disbanded years ago and could not have tested or approved Westech's impactor.

23. Westech's actions risk serious consequences. While it copied the appearance of the NGI, Westech's product literature indicates that the functional characteristics of its impactor differ in a critical regard—Westech's impactor has removable and adjustable nozzles. The Consortium rejected removable nozzles in development of MSP's impactor due to the potential for introducing variability into the measurement process. Even slight differences in the shape of the cups, placement of nozzles, or size of holes in the impactor will produce results that differ from the NGI. Westech's design will likely produce key differences in measurement conditions, leading to results from Westech impactors that differ from MSP's NGI device.

24. As a result, Westech's conduct threatens to undermine the entire purpose of the Consortium, and the competitive advantage of the NGI device, by eliminating the uniformity created by the use of the NGI device for all particle measurements. By selling visually identical, but functionally different, impactors, Westech will introduce the same uncertainty and variability into the measurement process that prompted the Consortium to have MSP develop the NGI device. Among other consequences, regulators may once again have to scrutinize measurement techniques and delay approval of medicines. Testing data could be invalidated. The last decade of progress in accurate and reliable particle measurement could be lost.

25. Companies needing an impactor should have an honest choice between the real, established, and approved NGI device sold by MSP and any alternative impactor. Any company that requires the benefits of uniform and officially accepted measurement

devices will choose the NGI device. Westech threatens to trick consumers into unwittingly buying a product that deviates from the proven and approved standard.

26. MSP vigorously safeguards its well-earned reputation for quality, reliability, and integrity. In particular, the NGI device is a leading product for MSP and an integral part of its reputation. MSP is known for getting cascade impactors and particle measurement exactly right. Westech should not be able to use MSP's trademarks and designs to profit from that reputation. If not stopped, Westech could succeed in tarnishing that reputation and the good will that MSP has spent more than 20 years fostering.

Further your affiant sayeth not.

s/ Daryl Roberts
Daryl Roberts

Subscribed and sworn to before me
this 12th day of June, 2007.

s/ Daniel John Jordan
Notary Public

My Commission Expires Jan. 31, 2011.

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